

# Role of Designated Institutes within the CIPM MRA

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## **Further information**

This Guide replaces the former EURAMET Guide No. 11 “National Metrology Infrastructure in EURAMET Member Countries - An Analysis and Recommendations”. For consultation purposes Guide No. 11 is still available.

For further information about this Guide, please contact the EURAMET Secretariat ([secretariat@euramet.org](mailto:secretariat@euramet.org)).

## Role of Designated Institutes within the CIPM MRA

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## Role of Designated Institutes within the CIPM MRA

The objective of the document is to summarise the role of DIs within the CIPM MRA, their duties and responsibilities, as well as their interactions within national metrology systems and their NMIs. It emphasises the importance and value of DIs, acting at the same metrological level and under the same strict requirements as NMIs. These activities are much broader in scope and conceptually different and more demanding than just calibration activities. The paper aims to facilitate the operations of DIs, designation processes at a national level, managing processes at the RMO (EURAMET) level and interactions with BIPM (and CIPM). The paper is based on existing EURAMET and BIPM documents, EURAMET questionnaires and is actually a compilation of current good practices and experiences of operation.

## Introduction

National Metrology Institutes (NMI) have the prime responsibility of being the source of traceability of the highest metrological level to the SI, or if this is not yet feasible, to other internationally agreed references, for metrology users in their country and adequate to their needs. This comprises the development, maintenance and dissemination of national measurement standards traceable to the SI, or when this is not (yet) possible, to other internationally agreed references. A major part of this work is the international recognition of these measurement standards and of the calibration and measurement reports and certificates issued on the basis of internationally assessed and approved Calibration and Measurement Capabilities (CMC) in accordance with the rules laid down in the CIPM MRA.

In many countries the NMI shares this responsibility with one or more Designated Institutes (DI), which are like the NMI operating at the top of the national metrology system. DIs play a crucial role in complementing the fields of activities of the NMI and bring in expertise in metrological areas not covered by the NMI, thus making an efficient use of the available national resources. It is therefore in the highest interest of EURAMET to achieve effective DI participation by ensuring that they operate in full compliance with EURAMET's expectations and the relevant rules for holding national measurement standards. Whilst a common understanding of metrological activities has been developed amongst NMIs over many years of fruitful and continuously convergent cooperation, in the case of DIs a much wider range of understanding and *modus operandi* may be observed.

The purpose of this paper is to provide a focused description of the activities that DIs (and also NMIs) are expected to provide within the framework of EURAMET. This also takes into account the criteria to be fulfilled in submitting CMC claims on the basis of the resolutions 28/1 and 28/2 of the 28<sup>th</sup> JCRB meeting (see annex B) [4], EURAMET Guide 10 [3] and 11 [2], CIPM 2009-24 ("Traceability in the CIPM MRA"). It is also in line with CIPM 2007-11 [6].

The paper gives guidance and recommendations to

- 1) National authorities on the decision process for the designation of a DI and its sustainable operation.
- 2) DIs on their role in the CIPM MRA and EURAMET's expectations to them.
- 3) NMIs for an effective cooperation with DIs within the national metrology system.
- 4) EURAMET TC's and authorities for the effective integration of DIs to the activities of EURAMET.

## **1. Situation of DIs in the CIPM MRA and in EURAMET**

### **1.1. DIs within the CIPM MRA**

- 1.1.1. The CIPM MRA introduced the concept of the “Designated Institute” (DI) as responsible for certain national standards and associated services that are not covered by the activities of the “traditional” NMI [1].
- 1.1.2. Each country participating in the CIPM MRA is entitled to designate such institutes. The designation is done by the authorised body of the country [8, 9]:
  - a) government / responsible ministry or authority, or
  - b) coordinating NMI, if authorised to do so by its government
- 1.1.3. BIPM will list the new DI in the KCDB, Appendix A of the CIPM MRA.
- 1.1.4. Within the CIPM MRA, DIs and NMIs are considered as being at the same metrological level, with respect to providing traceability to the SI and dissemination, consequently having to fulfil the same criteria in their activities related to the maintenance of national standards. All DIs must consider it their own responsibility to demonstrate conformity with the requirements of the CIPM MRA [11].
- 1.1.5. The designation as DI implicitly means the active participation in the CIPM MRA [9]. That means it is expected that a DI has succeeded in publishing CMCs in the KCDB, within a reasonable time after its designation.
- 1.1.6. Under the CIPM MRA designation is a sovereign right assigned to the appropriate national authority in the participating countries. Other than the proper completion of the designation nomination the BIPM is not in a position to judge whether an officially announced designation of a DI is in compliance with the criteria set for DIs in the CIPM MRA and subsequent CIPM documents. The CIPM MRA also assigns responsibilities (and workload) related to the DIs to the RMOs, for example Quality Management System (QMS) review and intra-regional review of CMCs. The RMOs are entitled to decide whether it is possible to execute these responsibilities for a given DI. Thus whilst ensuring the appropriateness of a DI is primary a national responsibility, in practice, in the framework of the CIPM MRA the RMOs play an important role in ensuring that DIs do in practice satisfy the CIPM MRA criteria.

### **1.2. Situation in EURAMET**

In 2011 an analysis was carried out on national metrology systems in EURAMET member countries, including the situation of DIs and the designation process [2].

- 1.2.1. Full membership in EURAMET is open to only one institute per country. For further institutes of the country, having the status of a DI in the KCDB, EURAMET offers the status as Associate (category A-DI). A formal registration of the DI as EURAMET Associate (category A-DI) is required before the DI becomes eligible to participate in the activities related to the CIPM MRA:
  - a. participation in KCs and SCs organised by EURAMET<sup>1</sup>,
  - b. review of the QMS of the DI within the TC-Q,
  - c. review of the CMCs of the DI within the concerned TC (AUV, EM, F, etc.).

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<sup>1</sup> Participation in KCs organised by CCs only requires being designated to BIPM and registered in the KCDB

- 1.2.2. Currently<sup>2</sup>, there are 150 DIs registered in the KCDB, half of them coming from EURAMET member states (75 A-DIs registered in EURAMET).
- 1.2.3. A survey carried out among EURAMET members in 2011 [2] revealed the following situation:
  - a. In approximately half of the EURAMET member countries DIs are established, with growing tendency.
  - b. DIs are established in all metrology areas, but the highest numbers are in the fields of ionising radiation (IR) and metrology in chemistry (MC).
  - c. In about half of the DIs the staff number is below 10. In most cases the DI is not an independent institute, but part of a larger institute dealing with other subject areas.
- 1.2.4. Over and above the fundamental *raison d'être* (the intention to disseminate metrological traceability nationally), in most countries strict criteria are used to establish the suitability of a potential DI, in order to assure the competent and sustainable operation of national standards and related CMCs by DIs [2]:
  - a. traceability to the International System of Units (SI)
  - b. successful participation in Inter-Laboratory Comparisons
  - c. stability and competence of staff
  - d. availability of resources
  - e. operation of a QMSThese criteria are in accordance with those of the CIPM MRA.
- 1.2.5. With the growing number of DIs in recent years, their impact to the National Measurement Systems and to EURAMET has increased significantly. Many DIs are fully involved with EURAMET activities and are well integrated in the organisation. Their expertise is crucial for many TC projects, for the review of CMCs and QMS, and for Joint Research Projects (JRP) of programmes such as EMRP and EMPIR. Representatives of DIs are or have been supporting EURAMET as TC-Chairs or BoD member.

### 1.3. Some observed issues

- 1.3.1. Maintenance of the CIPM MRA via the CMC recognition procedure is a highly resource intensive process. This represents a considerable burden to the RMOs and NMIs providing reviewers; expert time is provided at no charge. With the growing number of DIs the administrative burden for EURAMET, and in particular the workload in the TC-Q for reviewing the QMS of a high number of institutes (currently over 100) has increased. One should consider that the workload for reviewing the QMS of a small DI is similar to that for a large one or an NMI.
- 1.3.2. The fundamental difference between testing and calibration services, the aspect related to *dissemination* of the unit, is not recognised by all parties. This results in diverging interpretations of the “scope” of the CIPM MRA. In turn this poses the question of which kinds of CMCs should obtain their international recognition via the CIPM MRA, and which kinds would be better seeking this via accreditation by an accreditation body being a signatory of the ILAC MRA. In particular, this may be

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<sup>2</sup> June 2014



an issue in the case of small DIs within larger organisations, which do not have metrology as principal “business field” of the organisation.

- 1.3.3. With the increasing number of DIs, in particular of small DIs with a very limited scope of designation, the risk of fragmentation of the European metrology landscape and of overlapping activities among DIs in the same country is increasing.
- 1.3.4. DIs have often to provide complementary finances from their own budget to maintain their national standards, which might come from various sources [2]. A sufficient central national budget for national standards is generally not available, putting considerable risk on the sustainability of the established national measurement standards.

## **2. Metrological activities done by an NMI or DI**

### **2.1. Services that are typically delivered by NMIs and DIs for disseminating the SI**

- 2.1.1. Calibration of transfer measurement standards and measuring instruments and issuing of calibration certificates.
- 2.1.2. Certified Reference Materials (CRMs) production, including value assignment and certification, traceable to the SI or, where not (yet) possible, to other internationally agreed references.
- 2.1.3. Capability to assign traceable values to “in-house” reference samples of customers.
- 2.1.4. Validation of measurement methods/procedures used for disseminating the SI to the end user, for example, as a part of an accreditation process of a calibration laboratory.
- 2.1.5. Reference value assignment of Proficiency Testing samples (for own PT schemes and/or third party PT schemes).

### **2.2. Criteria for a CMC**

In particular to be considered for the proposal of a new DI and monitoring the performance of existing DIs:

- 2.2.1. The CMC claim is related to an existing or intended service.
- 2.2.2. The practical implementation of the service is demonstrated by being able to show for example existing cases of providing the service, certificates issued, etc.
- 2.2.3. There is a clear and on-going commitment to provide the service on a long-term basis, treating all customers on an equal footing.
- 2.2.4. The CMC provides a “dissemination of the unit” via calibration, value assignment or certified reference materials<sup>3</sup>.

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<sup>3</sup> this may be also providing a reference value for PT schemes.



- 2.2.5. The service can be at primary, secondary (or even lower) metrological level, fit-for-purpose in the national metrological hierarchy. But it has to be the reference at the national level.
- 2.2.6. As the national reference it represents the “connection” between the national metrology infrastructure and the international metrology system, described in the CIPM MRA, operating under the aegis of the Inter-Governmental Treaty of the "Metre Convention".
- 2.2.7. The validity of a CMC is checked in accordance with the rules described in the CIPM MRA and criteria and guidance given by the JCRB and approved by the CIPM. This requires active participation in international intercomparison exercises organised by CCs or RMOs. Attendance at meetings when comparisons are discussed is strongly recommended.
- 2.2.8. Criteria of complementarity: The CMCs offered by DIs must be complementary (in terms of measurands or ranges) but not overlapping to those of other DIs or the NMI in the country. It is the responsibility of the coordinating NMI or the national responsible authority for the national metrological infrastructure to guarantee the complementarity.

### **2.3. Realizing metrological traceability in the frame of CIPM MRA**

Metrological traceability is defined as the property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty [10].

In the case of institutes participating in the CIPM MRA and publishing CMCs in the KCDB, the following points concerning traceability should be considered [5]:

- 2.3.1. Traceability should be achieved only by one’s own primary realisation or via services offered by another recognized NMI/DI or laboratory<sup>4</sup> participating in the CIPM MRA, if CMCs of these services are published in KCDB. Details can be found on specific CIPM documents published by BIPM<sup>5</sup>.
- 2.3.2. Traceability at the national level cannot come from an institute not being NMI/DI (accredited or not-accredited)
- 2.3.3. Traceability at the national level cannot come from CRMs delivered by an institute not being NMI/DI.
- 2.3.4. A list with exceptions to this can be proposed by the relevant CC, approved by the CIPM, and published by the BIPM.
- 2.3.5. Traceability is not realized by obtaining “satisfactory” results in a comparison or in a PT scheme, but PTs are very useful for benchmarking performance and creating awareness of measurement competence.

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<sup>4</sup> In special cases, international organisations are able to participate in the CIPM MRA (IAEA, IRMM, ISA, WMO). NMIs and DIs may also take traceability directly from measurements made at the BIPM. The KCDB provides an automatic link to the relevant BIPM calibration services.

<sup>5</sup> For auxiliary influence quantities with uncertainties not contributing significantly to the uncertainty of the CMC, traceability may be obtained via accredited laboratories, recognised by the ILAC arrangement [5].

### **3. Recommendations**

#### **3.1. Recommendations to National Authorities**

National authorities should have in mind the following aspects before selecting and designating an institute:

- 3.1.1. Analyse carefully what are the needs for national standards in the country: Close collaboration within EURAMET provides an excellent and reliable alternative form to obtain traceability to the SI via the national measurement standards of other EURAMET members. This might be in particular relevant for metrology areas with a low demand in the country, which might not justify the use of scarce resources for the establishment and maintenance of new national standards on a primary level or even national standards that are not primary.
- 3.1.2. The designation of an institute in the private sector needs special attention. CIPM emphasises that “designating authorities should be aware that designating other laboratories in the private sector, may have a direct influence on the market position of other commercial companies in their own or even in other countries. Great care is needed to ensure that designation does not confer unfair market advantage.” (see [1], item 2.5). National authorities should consider the sustainability of DI’s human and financial resources, as well as the proper reference to metrology activities in the DI’s business plan.
- 3.1.3. The scope of the designation must be specified. A contractual arrangement between the national responsible authority for the metrological infrastructure or the coordinating NMI, if this NMI is authorized to do so, and the DIs of a country on the scope of designation is recommended for this purpose.
- 3.1.4. Besides the complementarity of the scope of designation to the scope covered by the NMI, the scope of designation should cover a certain range of services (e.g. a “category” defined by the corresponding CC). There is a risk that institutes are designated in a very limited range (covering very few or only one CMCs). One should avoid a very fragmented landscape, as it would be very difficult to control all these institutes and get them involved in the EURAMET technical activities.
- 3.1.5. Potential DIs should have already broad experience in accurate measurements in their field of designation and apply metrological principles, in particular with respect to traceability and measurement uncertainty. DI activities are on top of the national metrology system, different from testing activities being the reference of certain SI units in their country and responsible for their further dissemination. Consequently, compared to other activities like testing, this requires different uncertainty evaluation and appropriate quality systems!
- 3.1.6. Institutes should only be designated if they:
  - a. hold and maintain (potential) national measurement standards, and
  - b. have appropriate metrological experience and scientific expertise and
  - c. will act as a NMI in a well defined area of metrology, and
  - d. will deliver traceability in a well-defined metrology area, on an equal footing basis to all its customers.
- 3.1.7. It is essential to involve the coordinating NMI in the selection process of new DIs, to ensure that the scope of designation meets national requirements and is complementary to that of the NMI, and for validating the technical competence of

the DI before the designation. Further competent bodies in the country might be consulted.

- 3.1.8. Take care that financial stability of the DIs and appropriate financial resources (matching the required metrology level) for the maintenance of national measurement standards are assured on a long-term timescale. DIs should have appropriate financial stability and support as NMIs for their activities on national standards.
- 3.1.9. National authorities should follow-up the performance of the DIs.

## **3.2. Recommendations to Designated Institutes**

- 3.2.1. The DI should be aware of all the recommendations to National Authorities, as outlined in 3.1. and is expected to support their fulfilment.
- 3.2.2. Fulfil the criteria for national measurement standards, as outlined in 2.2. and 2.3. In particular for DIs having calibration or testing activities as key activities, it should be clearly understood that activities on national measurement standards are subject to additional requirements.
- 3.2.3. DIs are expected to be prepared to:
  - a. invest in staff and equipment to support their designation;
  - b. train specialized metrological staff in charge of their metrological activities;
  - c. have appropriate laboratory space available, which will be equipped with national measurement standards and other relevant equipment, maintained at fit-for-purpose laboratory conditions;
  - d. operate a QMS in line with ISO/IEC 17025 (and ISO 34 for CRMs), in line with requirements for calibration laboratories;
  - e. participate in metrological research such as EMRP, EMPIR, etc., if this is supported by their country;
  - f. participate actively in relevant RMO and Consultative Committee (Working Group) activities (comparisons and other activities);
  - g. participate regularly in KCs and SCs organised by the CCs or EURAMET;
  - h. develop and publish CMCs;
  - i. participate in the review of CMCs of other NMIs and DIs in their field of expertise;
  - j. disseminate units based on their CMCs;
  - k. deliver metrology knowledge transfer.
- 3.2.4. It is expected that DIs maintain regular interactions with their NMIs about their activities within the scope of designation as well as broader EURAMET and CIPM MRA issues.
- 3.2.5. DI experts are expected to actively participate in the relevant RMO TCs and, if applicable and if the DI has appropriate expertise, in the relevant CCWGs and CCs.
- 3.2.6. DIs that intend to participate in European metrology research programmes are expected to develop and maintain CMCs and to actively participate in the evaluation process and in the mutual exchange of information described above.

### **3.3. Recommendations to National Metrology Institutes**

- 3.3.1. Support the national authorities in the selection process of new DIs (see 3.1.5) and their proper integration in the national metrology infrastructure.
- 3.3.2. To have a mutual exchange of information between NMI and DIs regarding annual reporting to TC-Q and other relevant information.
- 3.3.3. Enable an appropriate participation of DIs in EURAMET activities, in particular in projects and meetings of TCs and SC and distribute all relevant information properly to the DIs.
- 3.3.4. In some countries it is good practice that a representative from the NMI participates in annual management meetings of the DI. Additionally, especially in cases where several DIs exist in the country, the NMI should arrange meetings with representatives from the NMI and the DIs for discussions on policy, plans, practical problems and solutions.

### **3.4. Recommendations to EURAMET**

- 3.4.1. Enable and encourage the participation of representatives of the DIs in the EURAMET GA.
- 3.4.2. Enable and encourage the active participation of experts from DIs in its TCs and other committees. The TC-Chairs should, whenever appropriate, make use of the possibility to invite representatives from nominated DIs as observers to TC or SC meetings.
- 3.4.3. Assess carefully whether claimed CMCs are covered by the QMS of a DI in compliance with ISO/IEC 17025 (calibration) and, if relevant, ISO Guide 34, and whether it is in compliance with the scope of designation.
- 3.4.4. Before submitting CMC claims for a new service, falling into an *area* of activity *which is new for the NMI or a DI*, an onsite-visit by peers is recommended, covering this area on the level of competence required for the claim; the relevant TC should take a decision. The accreditation scope of the DI will be also taken into account, if relevant.
- 3.4.5. The previous item means that in the case of a new DI, a technically oriented on-site visit by reputed, internationally recognized peers shall be carried out, as part of the QMS review of the TC-Q as soon as a first CMC claim is ready for submission. Before the on-site visit is carried out, the QMS should be operational.
- 3.4.6. If, after a period of 5 years, the DI has not made considerable progress to obtain CMCs, EURAMET should analyse with the DI and the corresponding NMI the reasons for this. In a given case, the possibility of a withdrawal of the associate status in EURAMET (A-DI) might be suggested (see [7] Part A, III.1(4)) and National Authorities might be asked to reconsider the designation. The same should apply, if a DI is not active in the framework of the CIPM MRA for a prolonged time.

3.4.7. EURAMET should work with the CCs, BIPM and the other RMOs on a clearer definition for what kind of quantities and measurements CMCs can be established. The difference between calibration (which can be included) and testing (which should not be included) requires careful consideration. EURAMET TCs and the CCs of the Metre Convention need to be consulted for this discussion [2].

## Annex A: EURAMET Acceptance criteria for DIs

### Policy

#### Acceptance Criteria for Associates

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According to the EURAMET Byelaws § 4 (3), "Only one institute per state can obtain EURAMET membership. For those states which have more than one institute responsible for maintaining national measurement standards, these institutes have to decide which of them will be the EURAMET member. Further institutes ... of this state ... can become Associates of EURAMET."

Although not stated as such in the byelaws, a principal reason for these Designated Institutes (DI) to become Associate of EURAMET is their participation in the CIPM-MRA in addition to other important EURAMET activities. Being Associate of EURAMET is a precondition to get their QMS and their CMC entries reviewed by the corresponding EURAMET Technical Committees.

The General Assembly (GA) agrees on the following criteria for an institute to become Associate of EURAMET:

1. It is a legal entity, or forms part of a legal entity.
2. It forms part of the national metrology system and is responsible for the maintenance of national standards and offers associated services which can be included as CMCs in the KCDB.
3. It intends to participate actively in EURAMET activities.
4. It is prepared to pay its dues and accept liabilities associated with participation in EURAMET activities, as stated in the EURAMET Byelaws and Rules of Procedure.
5. It is designated by the responsible national authority for metrology to the BIPM and is listed in the Appendix A of the KCDB.
6. It sends a written application to become Associate to the EURAMET Chairperson via the Delegate of the national EURAMET Member. The application has to be accompanied by the following information:
  - a. Copy of the formal designation by the national authority to the BIPM.
  - b. Short description of its legal status.
  - c. Description how the institute is embedded in the national metrology system.
  - d. Description of the national standards for which the institute is responsible (metrological field, quantity, scope) and the associated services.
  - e. Status of its QMS (in place, in preparation, not existing).

The decision on the application is taken by the EURAMET General Assembly (GA) according to the Byelaws §4 (5).

The Delegates ask the BoD to review the structure of the annual contributions to EURAMET (membership fees per country), considering the possibility to include a contribution from DIs which are Associates of EURAMET, in order to cover the administrative costs generated by their participation in the CMC and QMS review process and other EURAMET activities. The decision on the annual contributions has to be taken by the General Assembly according to the RoP Part A, 6(1).



## **Annex B: JCRB resolutions 28/1 and 28/2**

**28/1:** The JCRB resolves that laboratories should only be designated under the CIPM MRA when they have responsibility for national measurement standards and the dissemination of the units (i.e. providing traceability), as demonstrated by provision of appropriate and relevant services to customers.

**28/2:** The JCRB resolves that the QMS that must be in place prior to the acceptance of CMCs must be according to ISO/IEC 17025 (and ISO Guide 34 for CRMs) in line with requirements for calibration laboratories.



## Annex C: Glossary

A-DI	Associate of EURAMET, category DI
BIPM	International Bureau of Weights and Measures
BoD	Board of Directors
CC	Consultative Committee (of the CIPM)
CCWG	Working Group of a CC
CIPM	International Committee of Weights and Measures
CIPM MRA	Mutual Recognition Arrangement of the International Committee of Weights and Measures
CMC	Calibration and Measurement Capability
CRM	Certified Reference Material
DI	Designated Institute
GA	General Assembly
ILAC	International Laboratory Accreditation Cooperation
JCRB	Joint Committee of Regional Metrology Organisations and the BIPM
JRP	Joint Research Project
KCDB	Key Comparison Data Base
KC / SC	Key Comparison / Supplementary Comparison
NMI	National Metrology Institute
PT	Proficiency Testing
RMO	Regional Metrology Organisation
RoP	Rules of Procedure
QMS	Quality Management System
SC	Sub-Committee
SI	International System of Units
TC	Technical Committee
TC-Q	TC Quality

## Annex D: References

- [1] CIPM 2005-07: "NMIs and other Designated Institutes" (27-07-2005)
- [2] EURAMET Guide 11: "National Metrology Infrastructure in EURAMET member countries – an analysis and recommendations" (15-09-2011)
- [3] EURAMET Guide 10: "EURAMET and the operation of NMIs" (02-06-2008)
- [4] 28<sup>th</sup> JCRB Meeting, 3 – 4 April 2012, BIPM, Sevres, Minutes
- [5] CIPM 2009-24: "Traceability in the CIPM MRA" (revised 13-10-2009)
- [6] CIPM 2007-11: "CMCs – a paper by joint BIPM/ILAC working group" (07-09-2007)
- [7] EURAMET Rules of Procedure, Version 3.0 (22-05-2012)
- [8] JCRP-P-05: "Procedure for the registration of Designated Institutes participating in the CIPM MRA" (15-03-2012)
- [9] "Designated Institutes in the CIPM MRA", including the form for "Nomination of a DI" (March 2014)[ [www.bipm.org/JCRBCMCs/CMCList.jsp](http://www.bipm.org/JCRBCMCs/CMCList.jsp)]
- [10] JCGM 200:2012 "International vocabulary of metrology – Basic and general concepts and associated terms" (VIM)
- [11] CIPM 2005-06(REV): "The CIPM MRA: 2005 Interpretation Document" (June 2013)

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